VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

Laetitia Bernard
Regulatory Affairs Associate
NuVasive, Incorporated
10065 Old Grove Road
San Diego, CA 92131
Telephone: (858) 271-7070
Date Prepared: April 25th, 2000.

B. Device Name

Trade or Proprietary Name:	*NuVasive Facet Screw*
Common or Usual Name:	Posterior Facet Screw
Classification Name:	[Unclassified]

C. Predicate Devices

The subject device is substantially equivalent to the NuVasive, Inc. *Townley Transfacet/Intrapedicular Screw* (K994308).

D. Device Description

The *NuVasive Percutaneous Transfacet/Intrapedicular Screw* consists of a broad-headed, partially threaded screw designed to compact juxtaposed facet articular processes to enhance spinal fusion and stability. The non-threaded portion facilitates compression through a gliding hole technique. The screws are available fabricated from medical grade stainless steel (ASTM F136), or alternatively, Ti6Al4V titanium alloy, and are supplied in various lengths ranging from 25 to 60mm. In all sizes, the screws have a major diameter of 3.56mm (0.140") and a minor diameter of 2.60mm (0.102").

E. Intended Use

The *NuVasive Percutaneous Transfacet/Intrapedicular Screw* is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The *NuVasive Facet Screw* is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, and from C2 to S1, for treatment of any or all of the following:

(a) pseudoarthrosis and failed previous fusion;

(b) spondylolisthesis;

(c) spondylolysis;

(d) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies;

(e) degeneration of the facets with instability; and

(f) fracture.

The *NuVasive Percutaneous Transfacet/Intrapedicular Screw* is intended for conventional surgical placement, or alternatively, for percutaneous placement using the NuVasive *Guided Spinal Arthroscopy System.*

F. Comparison to Predicate Devices

As was established in this submission, the subject device is exactly the same as the NuVasive *Townley Screw* cleared by the agency for commercial distribution in the United States.

Engineering drawings and labeling have demonstrated that the subject device is identical to its predicate device in terms of design, materials of composition, manufacturing, packaging, indications for use, and method of use, excepting only the fact that it may be implanted by conventional surgical placement, and also by percutaneous implantation using the NuVasive *Guided Spinal Arthroscopy System.*

G. Summary of Non-Clinical Tests

Implantation surgery in a human cadaver has established that the subject device can be accurately implanted percutaneously using the *Guided Spinal Arthroscopy System.*

H. Summary of Clinical Tests

(Not Applicable).

I. Conclusions of Non-Clinical and Clinical Tests

Percutaneous placement of the subject device can be performed accurately with the NuVasive *Guided Spinal Arthroscopy System*, and with results equivalent, if not identical, to those achieved via conventional placement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Ms. Laetitia Bernard
Regulatory Affairs Associate
NuVasive, Inc.
10065 Old Grove Road
San Diego, California 92131

Re: K001323
Trade Name: NuVasive Percutaneous Transfacet/Intrapedicular Screw
Regulatory Class: unclassified
Product Codes: MRW
Dated: April 25, 2000
Received: April 26, 2000

Dear Ms. Bernard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): _____

Device Name: NuVasive, Inc. *Percutaneous Transfacet/Intrapedicular Screw*

Indications for Use:

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001323

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)